UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,814	09/12/2005	Dennis J McCance	21108.0016U2	8565

23859 7590 10/03/2008

Ballard Spahr Andrews & Ingersoll, LLP
SUITE 1000
999 PEACHTREE STREET
ATLANTA, GA 30309-3915

EXAMINER	
HARRIS, ALANA M	

ART UNIT	PAPER NUMBER
1643	

MAIL DATE	DELIVERY MODE
10/03/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,814	MCCANCE ET AL.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *1-18 and 20-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/19/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group VI (claim 19) in the reply filed on June 28, 2008 is acknowledged. The traversal is on the ground(s) that "[a]ll claims are directed to method of assaying for compounds that inhibit the activity of E7..." and "the Examiner has not met the burden for establishing a lack of unity of invention", see the Remarks, page 3, 1st full paragraph; and page 4, 3rd paragraph. This is not found persuasive because the methods of Group I and elected Group VI have different objectives and hence comprise different and distinct reagents and compounds. Moreover the method of Group I reads on assessing Akt activity and implementing an antibody, which are not necessitated in the elected invention. As noted in the Requirement mailed January 8, 2008 these methods differ in method objectives, endpoints, steps and parameters, see page 3, section 2. They are distinguishable from one another and require separate and distinct examination.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-31 are pending.

Claims 1-18 and 20-31, drawn to non-elected inventions is withdrawn from examination.

Claim 19 is examined on the merits.

Claim Objections

3. Claim 19 is objected to because of the following informality: it cites "E7-Akt" in section b. of the claim and "E7 Akt" in section c. of the claim. Applicants should cite consistent language in the claims, thereby citing one phrase that is constant in the claims and specification. Correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 19 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 19 is broadly drawn to a method of identifying an inhibitor of an E7-Akt interaction. The specification sets forth "...there are numerous variants of the E7 protein and Akt protein..." and amino acid sequence modifications can involve substitutional, insertional, as well as deletional variants, see section 102 beginning on page 26. It is art known that Akt is a family of enzymes including Akt1, Akt2 and Akt3, which have separate roles. The written description in this instant case has not been adequately defined. There is no SEQ ID number set forth in the claims which

corresponds to the either acronym, E7 or Akt, which would aid in clearly establishing what Applicants are in possession. The written description is not commensurate in scope with the claimed method including the broad terms, E7 and Akt.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (*See Vas-Cath* at page 1116). Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

Applicants are not required to disclose every species encompassed by a genus. For example as indicated in *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

Applicants are not entitled, nor is the specification enabled for the use of all E7 and Akt proteins that are undefined and uncharacterized. Applicants are not permitted to claim a method which embraces mutant proteins, hence not entitled to the wide

breadth of the claims at issue. And as Applicants' claims are written the recitations, "E7" and "Akt" could encompass variants, mutants and proteins from not only humans, but other animals. There is no description of the sites at which variability may be tolerated and there is no information regarding the relation of structure to function. Structural features that could distinguish the compounds in the genus from others excluded are missing from the disclosure.

This is insufficient to support the generic claims as provided by the Interim Written Description Guidelines published in the June 30, 2001 Official Gazette and posted December 27, 1999 at uspto.gov/web/menu/current.html#register.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claim 19 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent number 5,736,318 (issued April 7, 1998). U.S. Patent #5,736,318 discloses methods for identifying compounds capable of inhibiting interaction between human papillomavirus (HPV) oncoprotein E7 and a cyclin/cyclin-dependent kinase complex. A mammalian cell line containing the HPV E7 oncogene is regarded by the Examiner as the system comprising E7, wherein a test compound is added is order to assay for compounds having inhibitory activity for HPV oncoprotein E-7 stimulation of proliferation

of HPV-infected cells, see abstract; and column 7, line 43-column 8, line 15. These compounds would inherently inhibit E-Akt interaction.

8. Claim 19 is rejected under 35 U.S.C. 102(b) as being anticipated by WO 01/14584 A2 (March 1, 2001). The WO document discloses methods for identifying compounds capable of inhibiting interaction between human papillomavirus (HPV) oncoprotein E7 and a cyclin/cyclin-dependent kinase complex. A mammalian cell line containing the HPV E7 oncogene is regarded by the Examiner as the system comprising E7, wherein a test compound is added is order to assay for compounds having inhibitory activity for HPV oncoprotein E-7 stimulation of proliferation of HPV-infected cells, see abstract; page 11, lines 23-26. These compounds would inherently inhibit E-Akt interaction.

9. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alana M. Harris, Ph.D.
29 September 2008
/Alana M. Harris, Ph.D./
Primary Examiner, Art Unit 1643